REMARKS

The non-final Office Action mailed February 5, 2008 was reviewed and the comments of the Patent and Trademark Office were considered. Claims 1–20 were pending in the application. Claim 6 has been cancelled. Applicant reserves the right to pursue any cancelled claims in related applications. Claims 1–5 and 7–20 have been amended by this response, and new claims 21-27 have been added. Therefore, Claims 1–5 and 7–27 are pending in the application and submitted for reconsideration.

No new matter has been added by this Amendment. Support for the foregoing claim amendments and additions can be found in the specification as-filed, by way of example and not limitation, in the as-filed claims.

Rejections Under 35 U.S.C. § 112, 2nd Paragraph

The Office Action has rejected Claims 1, 2, 4–6, 8–12, 15, and 20 as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter.

The Office Action rejects Claims 1 and 20 for containing limitations allegedly lacking antecedent basis. Applicants have amended Claim 1 and 20 to clarify the antecedent basis, and thus request that these rejections be withdrawn.

The Office Action has rejected Claims 1, 2, 4–6, 8–12, and 15 as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter. Specifically, the Office Action states "[a] broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite...." The Office Action also alleges that Claims 1, 2, 4-6, 8-12, and 15 are indefinite because they "recite a broad limitation and also recite an additional limitation which is the narrower statement of the limitation" and/or because they "recite a broad range and also recite an additional limitation which is the narrower statement of the range." Applicants have cancelled Claim 6 and have amended Claims 1, 2, 4–5, 8–12 and 15 to clarify the invention, and thus request that these rejections be withdrawn.

In view of the amendments, Applicants respectfully request that all of the rejections under 35 U.S.C. § 112, 2nd paragraph be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

The Office Action has rejected (a) Claims 1–2, 5–12, and 17–19 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 4,902,513 ("Carvais") in view of U.S. Patent No. 6,699,506 ("Paillard"); (b) Claim 1–4 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Carvais in view of U.S. PGPub No. 2003/0099711 ("Meadows"); and (c) Claims 1–2, 13–16 and 20 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Carvais in view of U.S. PGPub No. 2002/0197327 ("Ulrich").

In levying an obviousness rejection under 35 U.S.C. § 103, the Examiner has the burden of establishing that the prior art references teach or suggests all the claim limitations. *See* M.P.E.P. §§ 2142, 2143. To determine obviousness, Examiners must consider (1) the scope and content of the prior art, (2) the differences between the claimed invention and the prior art, (3) the level of ordinary skill in the pertinent art, and (4) objective evidence relevant to the issue of obviousness." *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). In addition, the Supreme Court has pointed out the "import[ance of] identify[ing] a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (U.S. 2007). Here, the Examiner has not met the burden of demonstrating that the pending claims are obvious.

Applicants respectfully submit that the Office Action has failed to present a prima facie showing of obviousness, and that none of the pending claims are unpatentable over any of the cited references, either singly or in combination. Accordingly, Applicants request that the rejections under 35 U.S.C. § 103(a) be withdrawn.

35 USC § 103(a) Rejection Over Carvais In View Of Paillard

The Office Action has rejected (a) Claims 1–2, 5–12, and 17–19 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 4,902,513 ("Carvais") in view of U.S. Patent No. 6,699,506 ("Paillard"). Applicants submit that the combination of Carvais with Paillard neither teaches nor suggests all elements of the claimed invention.

For instance, neither Carvais nor Paillard teaches the instantly claimed percentages of (i) at least one film-forming polymer (P1) insoluble in the gastrointestinal tract fluids, present in

the amount of 50 to 90% by dry weight, based on the total weight of the coating composition, or (ii) at least one surfactant and/or lubricant present in the amount of 2 to 20% by dry weight, based on the total weight of the coating composition. In fact, the Office Action has not even pointed out where, if at all, Carvais and Paillard disclose the claimed percentages.

The Office Action alleges that it would have been obvious to combine the teachings of Paillard with Carvais to "result in a liquid suspension of [the drug] theophylline where the liquid phase was saturated with theophylline and the solid phase was coated microparticles containing theophylline." (Office Action at 5). Applicants respectfully disagree.

Carvais is directed to a "suspension comprising microcapsules of ... drug suspended in a saturated solution of said drug, the saturated level of said drug being maintained over a prolonged period of time for sustained release to the bloodstream..." (Carvais at col. 1, ll. 30 – 34). Thus, it is the saturated aqueous solution that controls the sustained release to the bloodstream. In fact, Carvais does not teach any type of microcapsule with a coating. Thus, the teaching of Carvais runs counter to the instant claims, where it is the *film coating* that controls the modified release of the active principle in the gastrointestinal tract.

Paillard is directed to dry microgranules comprising an active microsphere containing Milnacipran. Paillard neither teaches nor suggests suspending the microgranules in an aqueous solution at any time before the microgranules are administered to a patient.

For at least these reasons, Applicants submit that independent Claim 1 is patentable over Carvais in combination with Paillard. Each of dependent Claims 2–5 and 7–27 depends directly or indirectly from independent Claim 1, and each adds further patentable features to the patentable features of independent Claim 1. Applicants submits that Claims 1–5 and 7–27 are patentable over Carvais in combination with Paillard and respectfully request that this rejection be withdrawn.

35 USC § 103(a) Rejection Over Carvais In View Of Meadows

The Office Action has rejected Claim 1–4 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Carvais in view of U.S. PGPub No. 2003/0099711 ("Meadows"), allegedly because "it would have been obvious to one of skill in that art at the time the invention

was made to use the coating scheme as well as the particle composition of Meadows et al. to produce the sustained release theophylline suspension taught by Carvais." (Office Action at 6–7). Applicants respectfully disagree.

Meadows is directed to active principle bound to small particles of an ion-exchange resin, where the drug-resin complexes are then coated. (*See*, Meadows abstract). The structures of Meadows only work with a very narrow range of active principles because of the charge required. Ion-exchange resins are "ionic or capable of being ionized" and whether the resins can bind with an active principle depends upon the charge of the active principle and the method of binding. Thus, one with skill in the art would recognize that it would not be desirable to use the ion-exchange resins of Meadows to create drug formulations, because the formulations would be narrowly limited as to the type of active principle that may be used. In contrast, the instant invention may be used with any type of drug, and the charge of the active principle does not matter.

Further, the particles of Meadows do not have the same characteristics as the microcapsules of the instant invention. Indeed, Meadows teaches away from making the microcapsules of the instant invention. Meadows teaches that the coat weight and coat thickness vary the drug release time. Meadows teaches that for drug release within 1–4 hours, the complex should be coated "with a light coat... of about 10% to about 20% by weight of the dry resin," 6 – 10 hours is 30% to 35% by weight of dry resin, and 12 hours is 40 to 50% by weight of dry resin. (*See*, Meadows at paragraph 44).

The teachings of Meadows are in contrast to the instant invention for several reasons. First, the instant invention does not teach use of a dry resin core. Second, the drug release of the instant invention is not dependent upon the percent coat to core by weight. For instance, Example 1 has 700g of a core with 37.6g coat, thus the coat is 5.1% of the microcapsule by weight, but 50% of the drug release does not occur until about 4 hours. Example 3 has a core of 740g, a coat of 265.2g, thus the coat is 26% of the microcapsule by weight, but 50% of the drug release does not occur until about 3 hours.

Moreover, the combination of Carvais and Meadows does not teach all elements of the claims. For instance, neither reference teaches the instantly claimed percentages of: at least

one film-forming polymer (P1) insoluble in the gastrointestinal tract fluids, present in the amount of 50 to 90% by dry weight, based on the total weight of the coating composition. Meadows teaches that a polymer should be present in an amount of 44 – 47.5%, preferably from 45 – 46.5%. (*See*, Meadows at paragraph 40). Thus, Meadows teaches away from using polymers in the percentages required by the instant claims.

Further, neither reference teaches the use of at least one nitrogen-containing polymer (P2) present in an amount of 2 to 25% by dry weight, based on the total weight of the coating composition, as is required by the instant claims. In Meadows, the only time a nitrogen-containing polymer (P2) is used, it is as a solvating agent used to impregnate the drug-resin particles. (*See*, Meadows at paragraph 37).

In addition, neither reference teaches the use of at least one surfactant and/or lubricant present in the amount of 2 to 20% by dry weight, based on the total weight of the coating composition, as is required by the instant claims.

For at least these reasons, Applicants submit that independent Claim 1 is patentable over Carvais in combination with Meadows. Each of dependent Claims 2–5 and 7–27 depends directly or indirectly from independent Claim 1, and each adds further patentable features to the patentable features of independent Claim 1. Applicants submits that Claims 1–5 and 7–27 are patentable over Carvais in combination with Meadows and respectfully request that this rejection be withdrawn.

35 USC § 103(a) Rejection Over Carvais In View Of Ulrich

The Office Action has rejected Claims 1–2, 13–16 and 20 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Carvais in view of U.S. PGPub No. 2002/0197327 ("Ulrich").

The combination of Carvais and Ulrich does not teach all elements of the claims. Neither Carvais nor Ulrich teach the combination of (i) at least one film-forming polymer (P1) insoluble in the gastrointestinal tract fluids, present in the amount of 50 to 90% by dry weight, based on the total weight of the coating composition; (ii) at least one nitrogen-containing polymer (P2) present in an amount of 2 to 25% by dry weight, based on the total weight of the

coating composition; (iii) at least one plasticizer present in an amount of 2 to 20% by dry weight, based on the total weight of the coating composition; and (iv) at least one surfactant and/or lubricant present in the amount of 2 to 20% by dry weight, based on the total weight of the coating composition, all of which are required by the instant claims.

For at least these reasons, Applicants submit that independent Claim 1 is patentable over Carvais in combination with Ulrich. Each of dependent Claims 2–5 and 7–27 depends directly or indirectly from independent Claim 1, and each adds further patentable features to the patentable features of independent Claim 1. Applicants submit that Claims 1–5 and 7–27 are patentable over Carvais in combination with Ulrich and respectfully request that this rejection be withdrawn.

Conclusion Regarding 35 USC § 103(a) Rejections

Overall, whether taken individually or in combination, Carvais, Paillard, Meadows, and Ulrich fail to teach or suggest each limitation of independent Claim 1. Therefore, Claim 1 is not made obvious by these references. Each of dependent Claims 2–5 and 7–27 depends directly or indirectly from independent Claim 1, and each adds further patentable features to the patentable features of independent Claim 1. Applicants submits that Claims 1–5 and 7–27 are patentable over Carvais, Paillard, Meadows, and Ulrich and respectfully request that the rejections under 35 USC § 103(a) be withdrawn.

DOUBLE PATENTING REJECTIONS

The Office Action also provisionally rejects Claims 1-3, 4-10, 15, and 17-19 for nonstatutory obviousness-type double patenting over various applications by themselves or in view of Carvais. Applicants note that each rejection is provisional by procedure, and also notes that the applications used in the provisional rejections are pending. While the applicant does not acquiesce to the rejections, applicants nonetheless respectfully request that the present rejections for obviousness-type double patenting be held in abeyance until such time that the claims of the instant application are allowed.

CONCLUSION

Applicant believes the application is now in condition for allowance. Reconsideration and withdrawal of the rejections are requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned below.

Applicants submit concurrently a request for a three-month extension of time under 37 C.F.R. 1.136 and the accompanying fee. Please charge our Credit Card in the amount of $1,050, covering the fee set forth in 37 CFR 1.136(a). Please also charge our credit card $300 for 6 extra claims covering the fee set forth in 37 CFR 1.16(i). In the event that any additional extension of time is necessary to prevent the abandonment of this patent application, then such extension of time is petitioned. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-2228, from which the undersigned is authorized to draw, under Order No. 022290.0120PTUS.

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Respectfully submitted,

Patton Boggs LLP
8484 Westpark Dr.
9th Floor
McLean, VA 22102
(703) 744-8000
(703) 744-8001 (fax)

By _____
Jennifer L. King
Registration No.: 46,828
Attorney for Applicants